



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: INADA et al.  
Title: PHARMACEUTICAL COMPOSITION FOR  
ANGIOTENSIN II-MEDIATED DISEASES  
Appl. No.: 10/781263  
Filing Date: 02/19/2004  
Examiner: D. Lambkin  
Art Unit: 1626

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of the documents known to Applicants or cited by or submitted to the U.S. PTO in parent application Serial No. 08/351,011, filed 12/07/1994, now U.S. Patent No. 5,721,263.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98, except as noted below.

As provided in 37 CFR §1.98(d), copies of the Documents A1 – A8, A11 – A13, A15-A35 are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be

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appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

#### **RELEVANCE OF EACH DOCUMENT**

The relevance of Documents A1 – A8, A11 – A13, A15-A35 is explained in the parent application.

Documents A9, A10, A14, A31, and A36 – A46 relate to opposition proceedings in the European Patent Office regarding corresponding European Patent No. 0 753 301.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

#### **FEE**

A fee in connection with submission of an information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

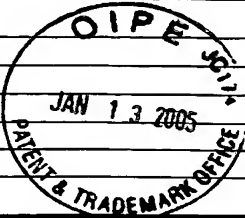
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet <b>1</b> of <b>2</b>		Application Number: 10/781263 Filing Date: 02/19/2004 First Named Inventor: Yoshiyuki Inada Group Art Unit: 1626 Examiner Name: D. Lambkin Attorney Docket Number: 087147-0494			

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	4,139,633		BRUNNEL ET AL.	02/1979	
	A2	4,880,804		CARINI ET AL.	11/1989	
	A3	4,895,846		POINDEXTER ET AL.	01/1990	
	A4	5,128,356		NAKA ET AL.	07/1992	
	A5	5,162,326		NAKA ET AL.	11/1992	
	A6	5,183,899		NAKA ET AL.	02/1993	
	A7	5,250,554		NAKA ET AL.	10/1993	
	A8	5,284,661		MORIMOTO ET AL.	02/1994	
	A9	5,164,407		GREENLEE ET AL.	11/17/1992	
	A10	5,196,444		NAKA ET AL.	03/23/1993	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A11	EP	0154009			09/1985		
	A12	EP	0279750			08/1988		
	A13	EP	0312157			04/1989		
	A14	EP	0400835 /	A1	MERCK & CO., INC.	05/1990		
	A15	EP	0430300			06/1991		
	A16	EP	0434038			06/1991		
	A17	EP	0445811			09/1991		
	A18	EP	0459136			12/1991		
	A19	EP	0483683			05/1992		
	A20	EP	0490587			06/1992		
	A21	EP	0501892			09/1992		
	A22	EP	0518033			12/1992		
	A23	EP	0520423			12/1992		
	A24	EP	0537937			04/1993		
	A25	GB	2270841	A		03/1994		
	A26	WO	91/00277			01/1991		
	A27	WO	91/00281			01/1991		
	A28	WO	92/10097			06/1992		
	A29	WO	93/17685			09/1993		
	A30	WO	94/09778			05/1994		
	A31	EP	0 324 377 /	B1	E.I. DU PONT NEMOURS AND COMPANY	07/19/1989		

 Examiner  
Signature

 Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/781263
				Filing Date	02/19/2004
				First Named Inventor	Yoshiyuki Inada
				Group Art Unit	1626
				Examiner Name	D. Lambkin
				Attorney Docket Number	087147-0494
Sheet	2	of	2		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>6</sup>
	A32	BERGLUND ET AL., "Low Doses of Hydrochlorothiazide in Hypertension Antihypertensive and Metabolic Effects," <i>Europ. J. Clin. Pharmacol.</i> , vol. 10, pp. 177-182 (1976).		
	A33	BEERMANN ET AL., <i>Europ. J. Clin Pharmacol.</i> , vol. 13, pp. 195-201 (1978).		
	A34	KINUGAWA ET AL., "Effects if a nonpeptide angiotensin II receptor antagonist (CV-11974) on [Ca <sup>2+</sup> ]; and cell motion in cultured ventricular myocytes," <i>Europ. J. of Pharmacol.</i> , vol. 235, pp. 313-316 (1993).		
	A35	MARTINDALE, The Extra Pharmacopoeia, 13 <sup>th</sup> Edition, pp. 368 & 374, 1993.		
	A36	Notice of Opposition to EP 0 753 301 by Hexal AG, dated February 9, 2004.		
	A37	Translation of a Statement from Maiwald patentanwalts GmbH, dated February 6, 2004, in relation to Opposition of EP 0 753 301 by Hexal AG.		
	A38	Notice of Opposition to EP 0 753 301 by Strawman Limited, dated February 9, 2004.		
	A39	Annex to Notice of Opposition to EP 0 753 301, dated February 6, 2004, in relation to Opposition of EP 0 753 301 by Strawman Limited.		
	A40	ERHART ET AL., eds., "Pharmaceutical Preparations," <i>Arzneimittel</i> , Vol. 2, pp. 318-322 (1972).		X
	A41	GIFFORD, "Drug Combinations as Rational Antihypertensive Therapy," <i>Arch. Intern. Med.</i> , Vol. 133, pp. 1053-1057 (June 1974).		
	A42	ROSENMAN, "Combined Clonidine-Chlorthalidone Therapy in Hypertension – Two Year's Experience in 30 Patients," <i>Arch. Intern. Med.</i> , Vol. 135, pp. 1236-1239 (Sept. 1975).		
	A43	BRAUNWALD, ed., <i>Heart Disease: A Textbook of Cardiovascular Medicine</i> , 4 <sup>th</sup> edition, pp. 829-831 (1992).		
	A44	WEBER, "Clinical Experience with the Angiotensin II Receptor Antagonist Losartan – A Preliminary Report," <i>Am. J. Hypertens.</i> , Vol. 5, pp. 247S-251S (1992).		
	A45	<i>Physician's Desk Reference</i> , 47 <sup>th</sup> Edition, pp. 1741-1743, pp. 1112-1114, pp. 2356-2359, pp. 902-904, pp. 1457-1460, pp. 1591-1593, pp. 1621-1624, pp. 2359-2362, pp. 1593-1597, pp. 1615-1618 (1993).		
	A46	Translation of a Federal Supreme Court Decision, <i>Cosmetic Suntan Preparation</i> , File No.: X ZR 68/99, December 10, 2002.		

Examiner Signature		Date Considered	
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<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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